

**LOCAL ENHANCED SERVICE FOR
Administration of Goserelin Implant**

Service Level Agreement

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SIGNATURE

The practice will need to sign a combined single signature sheet for all Enhanced Services provided. This will constitute the agreement between the practice and the PCT in respect of all Enhanced Service, as specified within each individual Service Level Agreement

PRACTICE DETAILS

INTRODUCTION

All practices are expected to provide essential services and those additional services they are contracted to provide to all their patients. They are also encouraged to provide the Directed, National and Local Enhanced services to the populations they serve. The specification for this service is designed to cover the enhanced aspects of clinical care of the patient, which is beyond the scope of essential services.

SERVICE AIMS

This agreement is to cover the period commencing 1ST April 2009 to 31st March 2010.

To ensure that administration of goserelin implant is undertaken by appropriately skilled practitioners within primary care.

CRITERIA

This Local Enhanced Service Specification details the following criteria. The following pages contain some further guidance from the PCT on expected processes, outcomes and deliverables based on this process. On aspiring to this service practices are required to submit plans under each of these items to the PCT.

- i. Staff Competence
- ii. Review/Audit

Criteria One: Staff Competence

Details

- Professionals undertaking this service should have undertaken **appropriate training**.
- Those doctors who have previously provided services similar to the proposed enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.
- The GP(s) and Registered Nurses can provide evidence that they have the experience and qualifications to undertake the procedure/s and all personnel providing the service are competent to provide those aspects of the service for which they are responsible and will keep their skills up to date.

Criteria Two: Review/Audit

Details

- The services delivered by this LES will be subject to clinical audit and monitoring will be carried out as part of the annual review of the contract and as part of review of this LES
- Full details of number of procedures per member of staff per annum.

Product Information

Name of product: **Goserelin (Zoladex)**

Pharmaceutical form: 3.6mg or 10.8mg implant

Therapeutic Indications:

- (i) Prostate Cancer
- (ii) Advanced breast cancer in pre- and peri-menopausal women suitable for hormonal manipulation.
- (iii) Zoladex 3.6mg is indicated as an alternative to chemotherapy in the standard of care for pre-/ peri-menopausal women with oestrogen receptor (ER) positive early breast cancer.
- (iv) Endometriosis:
- (v) Endometrial thinning
- (vi) Uterine fibroids: In conjunction with iron therapy in the haematological improvement of anaemic patients with fibroids prior to surgery.

Dose and Administration

One 3.6mg implant every 28 days or 10.8mg implant every 12 weeks

Endometriosis should be treated for a period of six months only, since at present there are no clinical data for longer treatment periods. Repeat courses should not be given due to concern about loss of bone mineral density. In patients receiving Zoladex for the treatment of endometriosis, the addition of hormone replacement therapy (a daily oestrogenic agent and a progestogenic agent) has been shown to reduce bone mineral density loss and vasomotor symptoms.

For use in endometrial thinning, four or eight weeks treatment. The second depot may be required for the patient with a large uterus or to allow flexible surgical timing.

For women who are anaemic as a result of uterine fibroids, Zoladex 3.6mg depot with supplementary iron may be administered for up to three months before surgery.

Special warnings and precautions for use

Males

The use of Zoladex in men at particular risk of developing ureteric obstruction or spinal cord compression should be considered carefully and the patients monitored closely during the first month of therapy. Consideration should be given to the initial use of an anti-androgen (eg. cyproterone acetate 300mg daily for three days before and three weeks after commencement of Zoladex) at the start of LHRH analogue therapy since this has been reported to prevent the possible sequelae of the initial rise in serum testosterone. If spinal cord compression or renal impairment due to ureteric obstruction are present or develop, specific standard treatment of these complications should be instituted.

Females

The use of LHRH agonists in women may cause a loss of bone mineral density.

Following two years treatment for early breast cancer, the average loss of bone mineral density was 6.2% and 11.5% at the femoral neck and lumbar spine respectively. This loss has been shown to be partially reversible at the one year off treatment follow-up with recovery to 3.4% and 6.4% relative to baseline at the femoral neck and lumbar spine respectively although this recovery is based on very limited data.

In patients receiving Zoladex for the treatment of endometriosis, the addition of hormone replacement therapy (a daily oestrogenic agent and a progestogenic agent) has been shown to reduce bone mineral density loss and vasomotor symptoms.

Zoladex should be used with caution in women with known metabolic bone disease.

Zoladex may cause an increase in uterine cervical resistance, which may result in difficulty in dilating the cervix.

Currently, there are no clinical data on the effect of treating benign gynaecological conditions with Zoladex for periods in excess of six months.

Contraindications:

Pregnancy and breast-feeding

ONGOING MEASUREMENT & EVALUATION

The ongoing measurement is outlined in the various criteria in the previous section. **The services provided and scope of this LES will be reviewed with the practice as part of the annual contract monitoring process.**

In addition the practice is required to agree with the PCT this service specification/plan at the start of the year.

FINANCE

This agreement is to cover the 12 months commencing 1st April 2009.

Practices will receive: -

£21.17 per implant